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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,196	01/17/2002	R. Eric Montgomery	04163-00138	6812

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EXAMINER	
KRASS, FREDERICK F	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/050,196	MONTGOMERY, R. ERIC	
	Examiner	Art Unit	
	Frederick F. Krass	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-42 and 49-81* is/are pending in the application.

4a) Of the above claim(s) *13-17,38-42 and 49-53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-37,54-63 and 70-81* is/are rejected.

7)☒ Claim(s) *64-69* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Previous Rejections

Unless explicitly repeated hereinunder, all previous rejections are withdrawn.

Duplicate Claim Warning

The examiner repeats the duplicate claim warning made at page 2 of the previous Office action, the text of which is incorporated by reference herein.

New Matter Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 70-81 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No support is seen in the specification as originally filed for the range "greater than 70% water", nor the range "greater than 80 percent water". Applicant apparently points to pages 7, 9, 11, 12 and 14 for support (Remarks, p. 8, ¶ 1), but the only water contents specifically disclosed therein appear to be the particular discrete values provided in the working examples, namely 72.8 to 86.5 percent. See Table 1 at p. 9. Working example 1 in the Provisional Application also discloses a value of 87.2 percent. (Table 2 at page 11 of the instant specification discloses an amount of 95.2 percent, but that is only for the second

part of a two part premix composition which, when the first and second parts were combined, would provide a whitening mixture having a much lower percentage of water).

Obviousness Rejection

Claims 18-37 and 54-63 were rejected as being unpatentable over Fischer (USP 5,098,303) in view of Goldemberg et al (USP 4,666,708).

This rejection is maintained.

Applicant argues that the primary reference differs factually in various respects from the instant claims and concludes:

> the fact that Fischer suggests a patient's teeth should be cleaned before whitening is irrelevant. Especially because Fischer does teach or suggest a method of cleaning a patient's teeth. It follows then that Fischer does not teach or suggest the [particular] method outlined by the Pending Application. (Remarks, p. 9, ¶ 4.)

Applicant presents similar reasoning in regard to the secondary reference. First, Applicant points to the fact that Goldemberg "identifies sodium benzoate, which is not an alkalizing agent, as the active reagent in the dental rinse formulation that loosens plaque." (Remarks, p. 10, ¶ 4.) Furthermore, Applicant continues:

> Goldemberg does not suggest that the 'bleaching reaction in a tooth using a chemical tooth-bleaching agent such as hydrogen peroxide can be significantly enhanced at a pH greater than 5.5. [at the tooth's surface].' (See the Pending Application, page 5, lines 20-24). Goldemberg is also silent with regards to the pH at the tooth's surface. Moreover, Goldemberg does not even mention tooth whitening. In fact, Goldemberg describes the subsequent use of a conventional dentrifice, rather than any specialized composition comprising 'a chemical tooth-bleaching agent such as hydrogen peroxide....' (See Goldemberg Column 8, lines 60-63; see the Pending Application, page 5, lines 21-22). One of skill in the art would know that conventional dentrifices do not contain hydrogen peroxide or hydrogen peroxide precursors. Only specialized dentrifices, such as dentrifices used for tooth whitening, may contain such peroxide compounds. Hence, Fischer combined with Goldemberg does not teach or suggest the method, outlined by the Pending Application.

The examiner does not agree with Applicant's reasoning. Applicant is merely pointing out what is lacking from each reference, i.e. engaging in a "piecemeal" analysis of the prior art and not addressing

the substance of the rejection as a whole. The fact that the secondary reference specifically discloses only "conventional" dentrifices, for example, does not mean that its cleaning method would not be useful as the cleaning method suggested by the primary reference. Fischer broadly suggests cleaning the teeth, a conventional step which would occur before applying the "specialized" carboxypolymethylene whitening gel.

Moreover, the rationale for modifying prior art teachings provided by the examiner need not be identical to Applicant's to support a fair case of obviousness. The Fischer et al cleaning step may be "irrelevant" in Applicant's eyes, but it is in fact a clear suggestion by the prior art and is thus objectively relevant (albeit not for Applicant's reasons) taken in view of Goldemberg. Likewise, the fact that Goldemberg might teach that the active ingredient is sodium benzoate does not negate the fact that the overall composition is alkaline and contains an alkalizing agent. Accordingly, the examiner reaffirms the reasoning provided in support of the rejection set forth in the previous Office action, the text of which is incorporated by reference herein.

The examiner does agree that certain unexpected results have been shown. See the "Allowable Subject Matter" section infra. It is the examiner's position with regard to claims 18-37 and 54-63, however, that the scope of those broadly claimed methods (lacking time or water content limitations) are not commensurate in scope with any such showing of unexpected results. As currently broadly constructed, claims 18-37 and 54-63 are inclusive of the methods suggested by the combined teachings of Fischer and Goldemberg.

Allowable Subject Matter

Claims 64-69 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 70-81 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 1st paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

As discussed in Applicant's response (Remarks, p. 9, ¶¶ 2 and 3) and throughout the instant specification, Applicant has unexpectedly discovered that alkaline pretreatment followed by bleaching unexpectedly permits the use of reduced concentrations of bleaching agent (and hence higher concentrations of water), while simultaneously reducing bleaching time. The advantages of these features are self-evident. Newly added claims 64-81 incorporate those unexpected features and thus would not be fairly suggested, taught or disclosed by the combined teachings of Fischer and Goldemberg, or any other prior art of record.

Regarding claim 70-81, Applicant may wish to recite the compositions as rinses, rather than attempting to specify a particular amount of water. For example, claim 70 could be amended to recite the method of claim 18 "wherein the whitening mixture comprises a rinse."

Technological Background Material

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

USP 5,611,690 discloses the process of rinsing to clean the teeth, followed by application of tooth bleaching gel, in a manner generally analogous to that suggested by the combined teachings of Fischer and Goldemberg. See col. 1, lines 30-37. The patent has an effective filing date later than that of the instant application, however, and thus is not available as prior art.

Action is Final, Necessitated by Amendment

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is as follows:

Monday: 10:30AM- 7PM;
Tuesday: 10:30AM - 7PM;
Wednesday: off;
Thursday: 10:30AM- 7PM; and
Friday: 10:30AM-7PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614